

NATIONAL CANCER INSTITUTE RAID MATERIAL TRANSFER AGREEMENT

The National Cancer Institute (NCI) Rapid Access to Intervention Development program (RAID) was designed to assist academic investigators with the development steps necessary to initiate clinical trials with their own discoveries. The program makes available to the academic research community, on a competitive basis, NCI resources for the development of drugs and biologics. A specific description of the NCI RAID program is available at <http://dtp.nci.nih.gov>.

This Agreement is made by and between the National Cancer Institute, an agency of the United States Government, (hereinafter referred to as “**NCI**”), and the _____ (hereinafter referred to as the “**RAID Institution**”). The name of the RAID Institution’s investigator is _____ (hereinafter referred to as the “**RAID Investigator**”). Collectively or individually, the NCI and the RAID Institution shall also be referred to as “Parties” or “Party.” The terms and conditions of this Agreement are as follows:

TRANSFER OF MATERIAL AND DATA

1. The RAID Institution agrees to transfer to NCI the following data and materials (collectively “**Institution Materials**”): _____

2. The Institution Materials will be used by the NCI in connection with the RAID Project (“**RAID Project**”) described with specificity as follows (use an attachment page if necessary): _____

3. The NCI agrees to transfer to the RAID Institution the following Clinical Material, Research Material or Research Data (collectively “**RAID Materials**”) resulting from approved NCI Cycle _____ **RAID Project, “Title”** _____. “**Clinical Material**” shall mean clinical material that is intended for use in the treatment or diagnosis of human subjects under a Food and Drug Administration (“**FDA**”) active Investigational New Drug Application (“**IND**”). “**Research Material**” and “**Research Data**” shall mean material and data that arise during the conduct of the RAID Project respectively.
 - a. _____
_____ ; and
 - b. Any additional RAID Materials that may be provided at a later time at the sole discretion of the NCI, will be described in an Appendix and shall be incorporated into this Agreement by reference.
4. If RAID Institution designates a third party to receive all or part of the RAID Materials then the RAID Institution will ensure that its designee complies with the terms of this Agreement.

CONFIDENTIALITY AND PUBLICATION

5. In all oral presentations or written publications concerning the RAID Project, each Party will acknowledge the other Party’s contribution of Institution Materials or RAID Materials unless requested otherwise. RAID Institution will acknowledge NCI’s contribution as follows:

“This project has been supported through the NCI-RAID Program of the Developmental

6. To the extent permitted by law, each Party agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of the other Party's written information about the RAID Project that is stamped "CONFIDENTIAL," except for information that was previously known to the other Party or that is or becomes publicly available or which is disclosed to the other Party without a confidentiality obligation. Confidential oral communications shall be reduced to writing within 30 days by the disclosing Party. This three (3) year term of confidentiality does not apply to information submitted in support of an IND. Such IND Data, as defined in Article 18 below, shall be kept confidential indefinitely until published. The Parties may publish or otherwise publicly disclose the results of the RAID Project, however, before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the RAID Project, the other Party shall be provided thirty (30) days to review the proposed publication or disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.
7. Results of the RAID Institution's research using RAID Materials shall be provided to the NCI at the time of public disclosure or within thirty (30) days of a request by the NCI, which ever occurs earlier.

USE OF INSTITUTION MATERIALS AND INTELLECTUAL PROPERTY

8. The Institution Materials represent a significant investment on the part of the RAID Institution. NCI therefore agrees to retain control over Institution Materials and further agrees not to transfer Institution Materials to other entities except as provided under this Agreement. When the RAID Project is completed, NCI will dispose of the Institution Materials as directed by the RAID Institution, or at NCI's discretion if no instructions are determined by NCI to be reasonably forthcoming. Institution Materials will be used for research purposes by the NCI for the RAID Project described above. Institution Materials may also be used by NCI's contractor or subcontractor in support of the RAID Project in accordance with Article 11. The Institution Materials will not be used for commercial purposes for screening, production or sale. The NCI agrees to comply with all Federal rules and regulations applicable to the RAID Project and the handling of the Institution Materials.
 - a. Are Institution Materials of human origin?

Yes
 No
 - b. If "yes" in 8.a., were Institution Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?

Yes (Please provide Assurance Number:)
 No
 Not Applicable (Explanation:)
9. The RAID Institution shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the RAID Project. The RAID Institution agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "**Government**") of the RAID Project, the RAID Institution or RAID Investigator conducting the RAID Project or any resulting product(s).
10. Normally, NCI will not acquire intellectual property rights to inventions made by its employees

with Institution Materials under RAID, unless RAID Institution and NCI mutually agree that to do so would be in the best interest of the RAID Institution. NCI will inform the RAID Institution of any such inventions, and after consultation with the RAID Institution, NCI will decide whether or not to file a patent application on any such invention. If NCI does file a patent application, the RAID Institution will be given an opportunity to negotiate for a license in accordance with the procedures set forth in 37 CFR Part 404.

11. In conducting a portion of the RAID Project, it may be necessary for NCI to utilize the services of one of NCI's contractors or subcontractors. NCI will inform the RAID Institution of the results of the NCI contractor's or subcontractor's research using the Institution Materials. With respect to NCI contractor or subcontractor inventions:
 - a. Normally such contractors and subcontractors may elect and retain title to subject inventions developed under the funding agreement under the provisions of the Bayh-Dole Act (35 U.S.C. § 200, et. seq.). In order to encourage applicants to participate in the RAID program, such contractors and subcontractors have agreed to include as a term and condition of their funding agreements, an agreement to offer to RAID Institution a first option to negotiate a license to subject inventions made using the NCI-RAID Institution's Research Material.
 - b. Certain other NCI contractors or subcontractors may be subject to a Determination of Exceptional Circumstances (35 U.S.C. § 202(a)(ii)), through which their rights in subject inventions made using the Institution Materials may be assigned to the Government. The RAID Institution may then apply to NIH for a license to the subject inventions.

USE OF EXCESS RAID MATERIALS

12. In the event a substance which contains/incorporates Institution Materials is produced by NCI (hereinafter referred to as "**Modified Derivative**") during NCI's use of the Institution Materials in support of the RAID Project, such Modified Derivative will be supplied by NCI to the RAID Institution for the RAID Institution's own research purposes upon request if available. In the event excess Modified Derivatives or excess RAID Materials are produced, NCI will have the right to supply such excess Modified Derivatives or excess RAID Materials to other non-profit institutions upon request, subject to the terms of an appropriate model NCI Agreement and subject to availability, including for use in clinical trials.
13. In exchange for the assistance provided by the NCI RAID Program, the NCI shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced, throughout the world by or on behalf of the Government for research or other Government purposes, RAID Institution inventions that protect or relate to RAID Materials. Any licenses granted by RAID Institution to a third party shall provide for the rights granted to the Government under this Article 13.

TERMINATION, EXPIRATION AND CONTINUATION OF RAID PROJECT

14. NCI may unilaterally terminate this Agreement at any time by providing written notice to the RAID Institution. The terms of Articles 4-22, shall survive early termination or expiration of this Agreement.
15. The RAID Institution shall notify NCI in writing if the RAID Investigator designated herein changes. Any change in designation of RAID Investigator shall become effective only upon a written amendment signed by the signatories to this Agreement. If the RAID Institution is unable or uninterested in continuing the RAID Project, NCI will have the right to continue development,

and the rights granted under Article 13 shall continue to apply even if this Agreement is terminated or expires. Additionally, RAID Institution agrees to transfer to NCI all information necessary to enable NCI to continue such development, including, but not limited to, transfer to NCI of the sponsorship of the RAID Institution filed IND at the FDA or corresponding foreign health authority. If the IND is an Investigator-held IND, then the RAID institution will be responsible for the following:

- (a) if the RAID Institution is interested in continuing the RAID Project, the RAID Institution will assure that the Investigator transfers sponsorship of the IND to the RAID Institution; or,
- (b) if the RAID Institution is unable or uninterested in continuing the RAID Project, the RAID Institution will assure that the Investigator transfers sponsorship of the IND to NCI.

Evidence of a lack of continued interest and required resources to work with the NCI RAID Program to progress in the development of the RAID Project toward the conduct of a clinical trial will serve to indicate cessation of RAID Institutions' commitment to development.

MISCELLANEOUS

16. RAID Materials, excluding Clinical Material, ARE BEING SUPPLIED WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Clinical Material is being provided for use as described in Article 19 below. Institution Materials ARE BEING SUPPLIED WITH NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. RAID Institution warrants that it has the right to supply Institution Materials to NCI for the RAID Project, and to the RAID Institution's knowledge, there are no encumbrances on the further clinical or commercial development of Institution Materials by RAID Institution or by NCI. NCI makes no representations that the use of the RAID Materials supplied will not infringe any patent or proprietary rights of third parties. No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this Agreement, except that the NCI, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).
17. If NCI is providing RAID Materials for the use in support of research on human subjects, RAID Institution agrees to the clinical terms in Articles 18–22.
18. RAID Materials may include data, including pre-clinical data, which has been identified by the NCI or its contractor or sub-contractor as data that is required to be submitted to the FDA in an IND (collectively "**IND Data**").
19. The NCI must be assured that the Clinical Material and IND Data it develops are used, communicated and reproduced appropriately and completely. The named RAID Institution agrees to retain control over this Clinical Material and IND Data and further agrees not to transfer the Clinical Material or IND Data to another person not under RAID Institution's direct supervision, other than investigators participating in clinical trials under an active IND supporting the use of the Clinical Material, without prompt written notice to NCI and subject to Article 4.
 - a. *Use of Clinical Material.* The NCI is providing this Clinical Material for use in human subjects where an active IND is on file with the FDA or under an active foreign equivalent application on file with the appropriate foreign health authority. Upon completion of all studies using the Clinical Material in human subjects, RAID Institution may use any remaining Clinical Material for non-clinical research purposes only.

- b. *Use of IND Data in support of an IND.* In order to ensure that the FDA or equivalent foreign health authority receives a complete data set for its review, RAID Institution agrees to ensure that all IND Data, in its entirety, as listed in Article 3, and any appendices, if provided, are included in a submitted IND or foreign health equivalent prior to the use of Clinical Material. RAID Institution agrees to ensure that any third party to which RAID Institution transfers IND Data provides written assurance that all such IND Data will be included in an IND and submitted to the FDA or foreign health equivalent. Upon request of NCI, RAID Institution will provide the NCI with a copy of such written assurance before RAID Institution shares or transfers the IND Data.
- 20. *Appropriate Approvals for Use of Clinical Material.* RAID Institution agrees to ensure that all appropriate approvals are obtained, including from the FDA, the Office for Human Research Protections (OHRP), and an appropriate Institutional Review Board (IRB) or other applicable approvals. RAID Institution will provide the NCI with copies of the FDA Acknowledgement Letter that the IND has been filed, any correspondence from the FDA relating to a possible Clinical Hold status on the IND, and the signed IRB approval letter before the Clinical Material is shipped.
 - a. *Use of Clinical Material and IND Data in Accordance with Applicable Regulations and RAID Institution Policies.* RAID Institution agrees that the clinical use of the Clinical Material and IND Data will be in accordance with clinical protocols approved by the appropriate IRB under a filed IND at the FDA or corresponding foreign health authority. RAID Institution agrees to submit all amendments to clinical protocols to the IRB and the FDA or corresponding foreign health authority.
 - b. *Use in accordance with Federal law.* RAID Institution agrees to ensure that this Clinical Material and IND Data are used in accordance with all Federal statutes and regulations, or other national law of the respective study site, that govern the use of investigational agents in clinical trials.
- 21. Upon request of NCI, RAID Institution agrees to provide all results of the research using the supplied Clinical Material and IND Data to NCI, including all publications as described in Article 6 and to provide NCI with copies of Annual Reports to the FDA or corresponding foreign health authority.
- 22. The Clinical Material that is provided by NCI to the RAID Institution will be used in accordance with this Agreement or disposed of in accordance with RAID Institution's policies, unless otherwise directed by NCI.

Signatures begin on the next page

ACCEPTED AND AGREED

FOR RAID INSTITUTION:

READ AND UNDERSTOOD BY RAID INSTITUTION'S INVESTIGATOR

Date	RAID Investigator

ACCEPTED AND AGREED FOR RAID INSTITUTION:

Date	RAID Institution Official

Date	RAID Clinical Investigator (if applicable and if different than "RAID Investigator")

RAID Institution's Official and Mailing Address:

FOR NATIONAL CANCER INSTITUTE:

ACCEPTED AND AGREED FOR NCI:

Date	Technology Transfer Specialist Technology Transfer Center, NCI

NCI Official and Mailing Address:

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).